

Serial No.: 09/830,666  
Atty. Docket No.: P66606US0

**REMARKS**

The Office Action mailed September 8, 2003, has been carefully reviewed and by this Amendment, claims 30-39 have been canceled without prejudice or disclaimer as being directed to a non-elected invention, claims 23, 25, 27 and 28 have been amended, and claims 40-44 have been added. Claims 22-29 and 40-44 are pending. In view of the following remarks, favorable reconsideration of this application is respectfully requested.

The Examiner objected to the drawings as containing informalities, and required a proposed drawing correction or corrected drawings. Applicant has submitted concurrently with this Amendment proposed drawing changes. Favorable consideration and entry thereof is requested.

The Examiner objected to the specification, abstract, claim 28 and the introduction to the claims as containing informalities. By this Amendment, Applicant has corrected the informalities noted in the specification and abstract, as well as others identified upon review, with a replacement abstract being submitted herewith on a separate sheet. Claim 28 has also been corrected herein.

The Examiner rejected claim 25 under 35 U.S.C. 112, second paragraph, as being indefinite. Claim 25 has been corrected herein.

Serial No.: 09/830,666  
Atty. Docket No.: P66606US0

The Examiner rejected claims 22-27 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,505,074 to Boveja et al. ("Boveja") in view of U.S. Patent No. 6,354,991 to Gross et al. ("Gross") and further in view of U.S. Patent No. 6,587,725 to Durand et al. ("Durand"). The Examiner also rejected claims 28 and 29 under 35 U.S.C. 103(a) as being unpatentable over Boveja in view of Gross and Durand, and further in view of U.S. Patent No. 5,199,430 to Fang et al. ("Fang").

The prior art as cited does not teach or suggest the presently claimed invention, as none of the references disclose the possibility or even the desirability of sensing or detecting electrical signals which are related to bladder activity from nerves innervating the bladder (or any other area), and providing information on bladder events. Nor do any of the prior art references disclose that it is possible or desirable to inhibit detrusor contraction. Each of the references will now be more specifically addressed.

Boveja discloses an implant designed to continuously stimulate a sacral nerve in order to treat urinary incontinence. There is no disclosure of detecting or sensing signals from nerves innervating the bladder, and no indication of the possibility of such sensing or detecting; instead, Boveja is an open loop system. Further, Boveja appears to completely disregard an important

Serial No.: 09/830,666  
Atty. Docket No.: P66606US0

problem associated with nerve stimulation, namely that, even though the stimulation pattern can be altered by a physician or the patient, continuous stimulation such as that taught by Boveja can lead to damage of the effected nerves by the bladder.

Gross discloses an implantable device for treatment of urinary stress incontinence and thus addresses an entirely different problem. Normally, both the bladder and the first part of the bladder outlet are situated in the abdominal cavity. An increase in abdominal pressure, as may result from coughing or laughing, acts on/affects the bladder as well as the outlet so that leakage does not result. In the case of stress incontinence, however, the abdominal pressure acts only on the bladder and not on the outlet. As a result, a cough increases the bladder pressure and will result in incontinence when the bladder pressure exceeds the closing pressure of the outlet.

Accordingly, Gross describes a system that detects a rise in the abdominal pressure and, in response, activates the closure mechanism of the bladder. The device as disclosed has electrodes "inserted into a muscle 32, in a vicinity of urethra 34 and bladder 36", preferably the levator ani muscle (column 11, lines 3-10). Other muscles are named, but there is no mention of connection to specific nerves, and thus no correlation to the problems addressed by the present invention.

Serial No.: 09/830,666  
Atty. Docket No.: P66606US0

In addition, Gross uses various sensors including EMG signals from a muscle, ultrasound, pressure sensors, acceleration sensors and strain and motor sensors. There is no disclosure of sensing using a nerve electrode of any type, let alone a nerve electrode placed on a nerve innervating the bladder, and therefore no suggestion of "detecting a nerve signal of a nerve innervating the bladder" as set forth in claim 22.

Again, the present invention does not treat stress incontinence but an overactive bladder. This is a very different indication and patient group. Unlike Gross, the present invention does not detect increases in abdominal pressure but instead detects increases in bladder pressure. Further, the response to the detection of the various signals is different in the present invention from that of Gross in that, in the present invention, the closure mechanism is not activated but, rather, the contraction of the bladder is aborted.

Hence, it must be concluded that the only feature common to Gross and the present invention is that of "generating an electrical signal" which Applicants respectfully contend is not sufficient to render the present invention obvious.

Durand discloses an apparatus and method for treating sleep apnea by stimulation of the hypoglossal nerve, a disclosure which involves a very different anatomical area from that of the

Serial No.: 09/830,666  
Atty. Docket No.: P66606US0

present invention. A signal in the hypoglossal nerve is detected and the stimulation is performed on the hypoglossal nerve; there is no indication that this method applies to treating an overactive bladder. Furthermore, there is no indication as to the obviousness of detecting a signal from a nerve innervating the bladder, processing the signal and determining a response stimulus delivered to another set of nerves (afferent nerves) to inhibit detrusor contraction of the bladder.

In sum, the patient population of Durand and that of the present invention is very different and Applicants contend that an extrapolation cannot be fairly made from the field of sleep apnea which would serve to identify the possibility of usefully sensing electrical signals in nerves innervating the bladder in order to inhibit detrusor contraction.

Fang discloses a method and apparatus for emptying the bladder by stimulation of the sacral nerve roots. Also described is the gaining of continence through activation of the urethral closure mechanism by selective stimulation of the somatic nerve fibers located in the ventral sacral nerve roots. This is unlike the present invention as well in that, like the contrast with Gross, with the present invention the closure mechanism is not activated but, instead, the detrusor (bladder) is prevented from contracting.

Serial No.: 09/830,666  
Atty. Docket No.: P66606US0

Activating the closure mechanism will indeed help prevent incontinence, but again the problem is different. The problem being solved by the present invention is not a weak closure mechanism, as in the prior art, but the need to control an overactive bladder. When the bladder contracts, the pressure inside the bladder increases, and leakage will occur when the bladder pressure exceeds the closure pressure. This is what is being prevented with the prior art methods. However, a side effect of increasing the closure pressure is that the bladder pressure will be high for elongated periods of time. High bladder pressure is dangerous in that it may cause kidney damage which will eventually lead to death. When the bladder contracts against a closed outlet, the bladder pressure will be even higher; so closing the outlet to prevent incontinence will result in higher bladder pressure and faster kidney deterioration. As a result, with the prior art methods the patient may stay dry, but his or her life expectancy is unacceptably reduced.

Further, Fang does not disclose any sensing or detecting, instead specifying that stimulation is applied to the sacral nerve. This is unlike the present invention which instead teaches the detection of a nerve signal being performed on the sacral nerves. Thus, the mere fact that these nerves are mentioned in Fang, without taking into consideration the completely contrasting use of

Serial No.: 09/830,666  
Atty. Docket No.: P66606US0

such nerves, overreads the teaching of Fang with respect to the present invention.

In summary, none of the cited references relate to a method for controlling an overactive bladder, and none disclose the detection of signals from nerves innervating the bladder in order to detect a bladder event. While Gross generates an electrical pulse, such pulse is not in response to a detected bladder event, and the stimulus is not delivered to afferent nerves to the bladder but to muscles in the general vicinity of the bladder. In none of the cited references is there any disclosure of the stimulation of afferent nerves, nor of stimulation to inhibit detrusor contraction.

For at least the foregoing reasons, claim 22 is patentable over the prior art. Claims 23-29 and 40-44 are also in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter contained therein.

With this Amendment, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially

Serial No.: 09/830,666  
Atty. Docket No.: P66606US0

invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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